



M E M O R A N D U M
OFFICE OF THE COUNTY MANAGER

ED&HS
AGENDA ITEM NO. 8 (B)

TO: Honorable Chairperson Barbara Carey-Shuler, Ed.D.
and Members, Board of County Commissioners

DATE: July 21, 2004

FROM: George A. Burgess
County Manager

A handwritten signature in black ink, appearing to read "George A. Burgess", written over the printed name.

SUBJECT: **Feasibility Report of
Importing Prescription
Drugs for Employees and
Using the Savings to Offset
Seniors' Drug Costs**

BACKGROUND

At the December 16, 2003 Board of County Commissioners meeting, Mayor Alex Penelas presented his proposal for the County to import Canadian prescription drugs for its employees and to use the savings to offset low-income seniors' drug costs. Subsequently, at its January 20, 2004 meeting, the Board of County Commissioners adopted Resolution No. R-113-04 directing the County Manager (through the Office of Countywide Healthcare Planning and General Services Administration Department's Risk Management Division) to conduct a feasibility study regarding the importation of Canadian prescription drugs for County employees and using the savings to offset low-income seniors' drug costs.

Prior to a feasibility study being conducted, the County Attorney's Office was directed to render an opinion on the legality of importing prescription drugs. In a March 15, 2004 letter, Assistant County Attorney Eugene Shy opined that, under current federal law, importing prescription drugs from Canada is not allowable (see Attachment A). However, Mr. Shy noted that the County could request the Department of Health and Human Services (HHS) Secretary to certify to Congress that Canadian prescription drugs are safe and cost effective. This would be necessary for the County to legally implement an importation program under current federal law. Upon HHS making the certification to Congress and promulgating supporting regulations, the County would be allowed to proceed with an importation program.

FEASIBILITY ISSUES

In determining the feasibility of a Canadian drug importation program, issues with legality and liability, safety, and cost-effectiveness were considered. As noted above, it is currently illegal to implement a drug importation program. Additionally, it is disconcerting to note that consumers are required to release Canadian pharmacies and pharmacy benefits managers from liability to their employees and contractors, including physicians, pharmacists, pharmacy technicians, nurses, receptionists and staff. This means, currently, that a U.S. consumer cannot make a legal claim for any errors or omissions against the Canadian pharmacy or the pharmacy benefits manager responsible for processing and transporting the prescription order.

Safety. In regards to safety concerns, the U.S. Food and Drug Administration (FDA) has the statutory responsibility to protect the public health by assuring the safety, efficacy, and security of drugs. The FDA has repeatedly stated that importing prescription drugs from other countries is both unsafe and illegal. It has expressed concern that importing prescription drugs into the U.S. increases

the likelihood of introducing drugs that are counterfeit, unapproved, recalled, improperly labeled, and generally unsafe. The FDA does not have safeguards to protect consumers from purchasing drugs from foreign sources whether they are purchased directly in another country or through the Internet. Several professional associations of physicians, pharmacists, and pharmaceutical manufacturers are similarly opposed to importing prescription drugs into the U.S.

Those in support of drug importations include numerous state and municipal governments, consumers and their advocacy groups, some national pharmacy chains (e.g., CVS and Walgreens), and participating Canadian pharmacies. However, they differ on their immediacy for importation. Those advocating for the immediate importation of prescription drugs from Canada observe that Health Canada, which is that Country's equivalent to the FDA, has regulations as stringent as the U.S., and thus, are safe. These statements have generally been made by state and local governments and Canadian pharmacy related organizations that would benefit from legal importation. The State of Illinois recently conducted a feasibility study on importing Canadian prescription drugs and concluded that it's "employees and retirees can safely purchase drugs from Canada."¹ More cautious statements are made by Families USA, a health care consumer advocacy organization that supports opening up importation of pharmaceutical products from advanced industrialized nations such as Canada. Families USA, CVS and Walgreens pharmacies argue that importation should be regulated by the federal government to ensure safety, just as other foreign products are regulated.

Cost-Effectiveness. To identify the potential cost savings to the County and the Public Health Trust (PHT), detailed cost and usage data was sought from the County's five health plans: AvMed, Cigna, Humana, JMH, and Vista. Deloitte Consulting LLP was enlisted to analyze the data. The data supplied by Cigna and AvMed was used as the basis for formulating the conclusions regarding savings. These two plans represent 75 percent of all covered lives (employees, retirees, and dependents). Canadian cost comparison data was provided by CanaRx Services Inc. (CanaRx), which is the Canadian Intermediary for the City of Springfield, Massachusetts. Springfield is the first U.S. municipality to implement a prescription drug importation program.

The analysis focused on maintenance drugs, since those are the prescriptions most likely to be filled through a Canadian mail-order program. Maintenance drug costs under the two plans represent approximately \$16.5 million. Utilization of existing mail-order programs to purchase maintenance drugs is limited and varies by plan. In the aggregate, the County currently spends about \$4.1 million (of the \$16.5 million) annually for mail-order maintenance prescriptions in AvMed and Cigna. The impact of the savings from the Canadian program depends on the extent to which County employees use the Canadian program, and the availability of the specific drugs utilized by County employees through the Canadian program. Approximately one-half of the County's expense for mail-order maintenance drugs would not be impacted by the use of the Canadian program since those drugs either do not appear on the listing of available drugs or because there are no savings to the County resulting from the purchase of those drugs through CanaRx. The remaining expenses were then analyzed to determine what the County would have paid for those prescriptions had the CanaRx program been utilized to purchase those drugs.

Only \$2 million of the \$4.1 million were considered in projecting possible savings. Assuming that all of the maintenance mail-order prescriptions currently included in the \$2 million figure migrate to the Canadian mail-order program, the projected savings to the County and the Public Health Trust is

¹ Illinois Department of Central Management Services, Office of Special Advocate for Prescription Drugs. October 27, 2003. *Report on Feasibility of Employees and Retirees Safely and Effectively Purchasing Prescription Drugs from Canadian Pharmacies*, page 2. (<http://www.affordabledrugs.il.gov/pdf/SpecialAdvocateCanadian10-27-03Final.pdf>)

approximately \$557,000. This further assumes that the County would waive the co-pays for these eligible mail-order drugs, resulting in a savings of approximately \$163,000 to employees, retirees and dependents. This model, however, assumes that the patient pays the cost of shipping and handling. If the County were to absorb shipping charges as well, savings to employees and retirees would increase to approximately \$214,000; while County savings would decrease to approximately \$487,000 (see Attachments B&C).

It is highly possible that waiving the enrollee co-pays and absorbing the shipping costs will increase participation in the mail-order program for qualifying members currently purchasing maintenance drugs through retail pharmacies. For every one percent of this "retail migration," an increase in the County's cost savings of \$50,619 would be achieved. For example, a ten percent shift from retail purchases to use of a Canadian mail-order program, would result in total anticipated savings of close to \$1 million to the County and PHT.

However, the projected savings are based purely on the costs of purchasing the drugs through a Canadian importation program vs. the cost under the current arrangements. There are other factors which must be considered in arriving at true savings to the County. Given that this program would be voluntary, no changes would be made in the current prescription drug benefits available through the existing health plans. Under the fully insured arrangements with the current HMO's, the County pays them a premium based on anticipated claims. Since they would have no way of predicting the amount of their prescription costs that would migrate to the Canadian program, it is unlikely they would reduce the premiums being charged to the County (at least until substantial data is developed to confirm the impact). Hence, the County would accrue no savings from the HMO plans. If the costs under their plans do come in lower because employees utilized the Canadian program, the HMO will not return the excess premiums to the County. The self-insured POS plan is the only program in which the County will actually recognize the savings as the County's costs are based on what is actually used. If prescription drug utilization in the POS decreased, the County would retain the savings.

In addition, there will be an administrative cost associated with offering the Canadian program. There will have to be a vehicle available to pay the Canadian Intermediary for the prescriptions that are billed. It is unclear at this time what level of administrative support would be required or what the cost of those services would be. However, any costs to administer the program would further diminish the projected savings.

STATE AND MUNICIPALITY PRESCRIPTION DRUG IMPORTATION EFFORTS

There has been a groundswell of states and municipalities investigating the feasibility of importing prescription drugs, including looking into other modes of prescription assistance. In fact, 22 state legislatures heard more than 40 drug importation bills this year. Nationally, mounting public pressure has made some headway with Congress with the advancement of bills that would allow the importation of prescription drugs. The HHS Secretary has recently predicted that Congress will pass legislation on the matter this year. Senate Majority Leader, William Frist, has stated that he will allow a prescription drug bill to be heard by the end of this year. The following represents a snapshot of various state and municipality activities in planning and implementing a variety of programs.

Illinois has conducted a feasibility study on State employees' use of Canadian vendors to purchase prescription drugs. The study underscored the HHS safety and cost effectiveness certification requirements to Congress. The conclusion was that Canadian drugs could be safely and effectively imported into the United States. It was estimated that the annual combined cost savings for the State and for employees would be \$90.7 million. Last December, the Governor of Illinois submitted a formal request to HHS asking its Secretary to certify that importing Canadian prescription drugs are

safe and cost effective. The Governor has also recently initiated a federal class action lawsuit filed against HHS and the Food and Drug Administration. HHS has recently responded that projects, such as that proposed by Illinois for certification, are not authorized under current law and that they present additional safety concerns.

Iowa has prepared a cost savings study as a precursor to more in-depth feasibility study. Iowa estimates a total annual savings of at least \$10 million on prescription drug costs for its employees and the State. Minnesota and West Virginia are also investigating ways to reduce prescription drug costs for state employees via a Canadian importation program.

New Hampshire, North Dakota, Wisconsin and Minnesota have developed websites directing their residents to Canadian mail-order pharmacies. Residents can then purchase mail-order drugs for approximately 35% less than in the United States. In the first three months of Minnesota launching its website, approximately 1,470 prescriptions have been filled by residents. The websites post legal disclaimers affording the respective states with protection from potential lawsuits. Rhode Island has piggybacked on Wisconsin's website by providing a link for Rhode Islanders.

North Dakota Senator Byron Dorgan has proposed establishing a pilot project to allow state-licensed pharmacists and drug wholesalers to purchase approved prescription drugs from licensed Canadian pharmacies and wholesalers. This represents a different mechanism than proposed by other states in which individuals would make their individual purchases with a Canadian company. Senator Dorgan has yet to submit his proposal to HHS for approval.

Springfield, Massachusetts is the first municipality to implement a Canadian prescription drug importation program for employees. Approximately 3,000 of Springfield's employees, their dependents, and retirees participate in the program. This represents about one-third of those who are taking maintenance drugs and about 15% of all who are enrolled in the City's health plan. This model requires the participating employees (and retirees and dependents) to purchase medication directly from a predetermined Canadian pharmacy benefits manager (PBM). The PBM coordinates services with a network of Canadian physicians and pharmacists. The medication is shipped to the participant and the municipality is billed for the cost of the drugs. Springfield created incentives to participate in their importation program by eliminating co-payments for Canadian prescriptions and not charging for mailing costs, while raising co-payments for import-qualified but domestically-filled prescriptions. Cumulative cost savings since its July, 2003 inception are estimated at 40% or approximately \$3 million over the initial 10-month period. A similar program in Burlington, Vermont, began in March for its employees. Both Springfield and Burlington utilize the Canadian pharmacy benefits manager, CanaRx Services, Inc., of Windsor, Ontario, for processing and shipping prescription drug requests.

Boston, Massachusetts is developing a Canadian prescription drug importation program for its employees. A later phase may include a program for its residents. The City anticipates a July, 2004 implementation. The municipalities of Leon County, Florida, Montgomery County, Maryland and Seattle, Washington are also investigating an importation program for their employees.

EXISTING PRESCRIPTION DRUG DISCOUNT PROGRAMS

While conducting its research, the Office of Countywide Healthcare Planning has determined that there are existing prescription assistance and discount drug card programs for seniors and low-income residents. Therefore, an alternative strategy to assist seniors in their drug costs was considered and is described in this section.

The cost of prescription drugs has produced significant hardships for seniors. In a 2001 survey across eight states, more than one fourth of seniors without health care coverage stated that they skipped medication doses to make their prescription last longer. More than one-third of those who lacked coverage and were suffering from one or more chronic health conditions (such as congestive heart failure, diabetes, or hypertension) reported to similarly stretch their medication. And twenty-five percent of seniors without health care coverage reported not filling a prescription due to cost.

Federal and state governments and pharmaceutical companies have programs designed to reduce seniors' burden on purchasing prescription drugs. First and foremost is the newly launched Medicare Prescription Drug Discount Card and Transitional Assistance Program. This program was enacted into law as part of the Medicare Modernization Act of 2003. Under this program, Medicare beneficiaries may voluntarily enroll with a Medicare-approved private company to receive a discount card on their prescription drugs. Seniors should obtain discounts between 10 and 25 percent. Additionally, low-income Medicare recipients may qualify for a \$600 annual credit toward their prescription drug purchases with extra discounts on purchases under the Transitional Assistance Program component. This program is intended as a stopgap measure until a broader prescription drug benefit begins January 1, 2006. It should be noted that current Federal law prohibits Medicare from negotiating prices directly with pharmaceutical manufacturers on behalf of beneficiaries. Further cost savings, both to the federal government and to Medicare beneficiaries would be expected if this prohibition were lifted.

At the state level, Florida's Silver Saver Prescription Drug Program provides low-income seniors age 65 and older with \$160 a month in prescription drug benefits. This 1115 Pharmacy Plus Waiver provides prescription drug assistance for those seniors who are between 88% and 120% of the federal poverty level. Program restrictions prevent someone who is receiving Silver Saver Prescription Drug program assistance from also enrolling in the Medicare Prescription Drug Discount Card and Transitional Assistance Program.

In Miami-Dade County, seniors would greatly benefit from these federal and state drug discount and assistance programs due to their high rate of poverty. Locally, there are 300,552 residents age 65 and older, of which almost one in every five is below the federal poverty level (56,794 or 18.9%). The vast majority of seniors age 65 and older (283,566 or 94.3%) are enrolled in Medicare. Locally, it is estimated that slightly fewer than 17,000 seniors are not enrolled in Medicare. Those who are not enrolled may either be eligible but have not applied, or may not meet the eligibility criteria for Medicare. To be eligible, seniors must have worked for at least 10 years in Medicare-covered employment and are 65 years old and a citizen or permanent resident of the United States.

In addition to federal and state prescription drug assistance programs, many pharmaceutical manufacturers have programs that offer free or reduced cost prescriptions to qualifying individuals. Eligibility criteria vary with the manufacturer and the drug. Several websites offer links to prescription drug assistance programs, including www.needymeds.com, and the drug industry association, PhRMA's patient assistance and drug discount program websites, www.helpingpatients.org and www.ayudandopacientes.org in Spanish. Each of PhRMA's 48 pharmaceutical manufacturer members provides some form of assistance. Currently, there are more than 1,400 individual medicines available. The State of Florida has a website that offers links to information about various prescription assistance and manufacturer discount card programs: <http://www.floridahealthstat.com/pdc.shtml>.

CONCLUSION

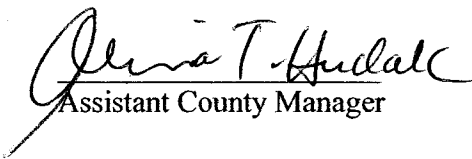
Cost-Effectiveness. Significant unknown factors thwart attempts to precisely determine the cost-effectiveness of implementing a mail-order prescription drug importation program. Perhaps the

most significant of these is the extent to which employees would migrate from retail to mail order purchasing. Other concerns include the unlikelihood that the fully insured health plans would initially lower their premiums based on the lack of baseline participation data for an importation program. Additional administrative support would likely be needed, further eroding cost savings.

Certification Request Letter. Consistent with the County Attorney's Office legal opinion, the Board of County Commissioners may choose to submit a letter to the Secretary of the Department of Health and Human Services (HHS) requesting that the HHS Secretary certify to Congress that Canadian prescription drugs are safe and cost effective. This is a necessary first step before the County can legally implement an importation program under current federal law.

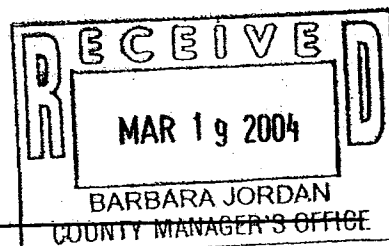
Outreach Program for Seniors. A mechanism already exists for educating seniors regarding the various public and private prescription drug programs. The Sunshine for Seniors program was created by the Florida Legislature to serve as a one-stop prescription assistance program aimed at helping seniors age 60 and older make informed decisions. Locally, the program is administered by SHINE (Serving Health Insurance Needs of Elders) volunteers through the Alliance for Aging, the local area agency on aging.

While awaiting federal approval to import Canadian prescription drugs, the Board of County Commissioners may decide that an outreach program for seniors and low-income residents be developed and promoted regarding enrollment information on existing prescription assistance and drug discount card programs. If directed by the County Commission, staff would work with the Alliance for Aging's Sunshine for Seniors program, as well as, Miami-Dade County departments to promote the outreach effort. The Department of Human Services and Team Metro are prepared to provide such outreach support, which could include the distribution of brochures and the provision of train-the-trainer instruction in providing clients and community groups with guidance and referral to appropriate prescription assistance and drug discount programs. Upon County Commission direction, staff could also pursue the opportunity to videotape a SHINE or Florida Department of Elder Affairs speaker for subsequent viewing on Miami-Dade TV.


Assistant County Manager

Attachment

MEMORANDUM



TO: Barbara Jordan
Assistant County Manager

DATE: March 15, 2004

FROM: Eugene Shy, Jr.
Assistant County Attorney

RE: Importation of Prescription
Drugs from Canada

At its January 20th meeting, the Board of County Commissioners adopted Resolution No. R-113-04 (the "Resolution") directing the County Manager¹ to conduct a feasibility study regarding importation of Canadian prescription drugs for County employees and senior citizens. The Resolution provides, however, that the Manager shall not commence the study until the County Attorney's Office renders an opinion regarding the legality of such importation.

Importation of prescription drugs from Canada is not allowable under the Federal Food, Drug and Cosmetic Act² until the Secretary of the Department of Health and Human Services (the "HHS Secretary") certifies to Congress that the prescription drugs from Canada are safe and cost effective and promulgates regulations for importation.

Until the HHS Secretary makes the requisite certification to Congress, the provisions of the Act regarding importation of Canadian prescription drugs are not effective and importation remains prohibited. Notwithstanding the foregoing, the following series of actions may be taken or must occur to achieve the goal of a County plan to import Canadian prescription drugs for County employees and senior citizens:

1. The County should request the HHS Secretary to certify to Congress that the prescription drugs imported from Canada are safe and cost effective. The Governor of Illinois has taken this step.³
2. The HHS Secretary then must make the statutorily-required certification to Congress.

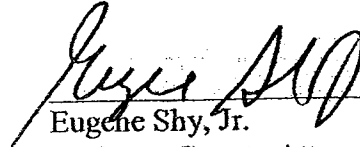
¹ Through the Office of Countywide Healthcare Planning and General Services Administration Department/Risk Management Division.

² 21 U.S.C. §301 et seq. The United States Food and Drug Administration (FDA) is the federal agency, within the jurisdiction of the Department of Health and Human Services, responsible for ensuring that drugs and medical devices are safe and effective and that these products are honestly, accurately and informatively represented to the public.

³ On December 22, 2003, Illinois Governor Rod R. Blagojevich sent a letter to Tommy Thompson, the HHS Secretary, requesting that the HHS Secretary under the Act make the certification to Congress and grant waivers of the prohibition for Illinois to import prescription drugs from Canada.

3. If the HHS Secretary makes the certification to Congress, then the importation provisions of the Act will become effective without additional legislative authority.
4. The HHS Secretary must promulgate regulations as provided in the Act.

If you should have additional questions, please feel free to contact me.


Eugene Shy, Jr.
Assistant County Attorney

ES/dg

Attachment B

The chart below depicts the incremental savings to the County as the migration from retail to mail-order purchasing at CanaRx grows:

% Retail Migration	Maximum Employer Savings	Maximum Employee Savings
Current Mail Order Only	\$556,696	\$163,341
1%	\$609,726	\$174,379
2%	\$662,756	\$185,417
3%	\$715,786	\$196,455
4%	\$768,816	\$207,493
5%	\$821,846	\$218,532
6%	\$874,876	\$229,570
7%	\$927,906	\$240,608
8%	\$980,936	\$251,646
9%	\$1,033,966	\$262,684
10%	\$1,086,996	\$273,722
20%	\$1,617,296	\$384,104
30%	\$2,147,596	\$494,485
40%	\$2,677,896	\$604,867
50%	\$3,208,197	\$715,249
60%	\$3,738,497	\$825,630
70%	\$4,268,797	\$936,012
80%	\$4,799,097	\$1,046,393
90%	\$5,329,397	\$1,156,775
100%	\$5,859,697	\$1,267,156

Attachment C

Should the County decide to absorb the shipping and handling costs, the incremental savings associated with this policy would be as follows:

% Retail Migration	Maximum Employer Savings	Maximum Employee Savings
Mail Order Only	\$487,047	\$213,906
1%	\$537,666	\$231,921
2%	\$588,286	\$249,936
3%	\$638,905	\$267,951
4%	\$689,525	\$285,967
5%	\$740,144	\$303,982
6%	\$790,763	\$321,997
7%	\$841,383	\$340,012
8%	\$892,002	\$358,027
9%	\$942,622	\$376,042
10%	\$993,241	\$394,057
20%	\$1,499,435	\$574,209
30%	\$2,005,630	\$754,361
40%	\$2,511,824	\$934,512
50%	\$3,018,018	\$1,114,664
60%	\$3,524,213	\$1,294,815
70%	\$4,030,407	\$1,474,967
80%	\$4,536,601	\$1,655,119
90%	\$5,042,796	\$1,835,270
100%	\$5,548,990	\$2,015,422